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No. 74-431

FILED
FEB 13 1975
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IN THE

# Supreme Court of the United States

OCTOBER TERM 1974

VITA FOOD PRODUCTS OF ILLINOIS, INC.,

Petitioner,

vs.

UNITED STATES OF AMERICA,

Respondent.

## ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

## REPLY BRIEF FOR PETITIONER

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## REPLY BRIEF FOR PETITIONER

On October 16, 1974, Petitioner, Vita Food Products of Illinois, Inc. ("Vita"), filed a Petition for Certiorari to the United States Court of Appeals for the Seventh Circuit in the instant case. On February 6, 1975, the Solicitor General of the United States filed a Brief for the United States in Opposition. This Reply Brief is directed to some of the more important points raised by the United States in opposition to the Petition for Certiorari.

1. The United States does not dispute that this case presents an important "question in the administration of the Food, Drug and Cosmetic Act" (*62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951); Supreme Court Rule 19 1(b)), nor does it deny that the decision of the Court of Appeals for the Seventh Circuit has ramifications that extend far beyond the particular factual circumstances of this case. See generally Brief Amicus Curiae on Behalf

of the National Fisheries Institute, Inc., in Support of the Petition for Writ of Certiorari. In view of these circumstances, the argument that the Petition should be denied merely because there is no conflict among the Courts of Appeals is unpersuasive.*

2. A principal thrust of the argument of the United States is that the traces of DDT and dieldrin found in Vita's smoked fish are "food additives" within the meaning of Section 201(s) of the Federal Food, Drug and Cosmetic Act ("FDCA") because they "become components of petitioner's chubs as a result of the intended use of these chemicals . . . . These residues [of DDT and dieldrin] are unavoidable and are in no sense unintended or unintentional." Brief in Opposition, p. 5. This argument is, at best, misleading.

Section 201(s) of the FDCA, 21 U.S.C. § 321(s), provides:

> "The term 'food additive' means any substance the *intended use* of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance *intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food* . . . ." (Emphasis added.)

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* The United States correctly notes (Brief, p. 4) that four courts have passed upon the question of statutory construction raised in the present case. As pointed out in the Petition (p. 24), however, only the decisions of the District Court and the Court of Appeals in this case have presented a full and extensively-reasoned analysis of the statutory language in question and its legislative history. The other two district court decisions contain no such analysis. Thus the two courts that have considered the matter in depth have reached diametrically opposed conclusions.

Thus Section 201(s) makes clear that a "food additive" is a substance that is "intended for use" *in the course of the food production or distribution process.* In the present case, it is undisputed that neither Vita, nor any other person or entity connected with the catching, processing, or distributing of the fish in question, intended to use, or did in fact use, DDT or dieldrin in any form or in any manner. These substances do *not* become components of Vita's fish during any stage of the processing or distribution process, for it is undisputed that DDT and dieldrin migrate to fish while they exist in their natural state in Lake Michigan prior to the time that they are caught.

While both the statutory language of Section 201(s), and the legislative history of the Food Additives Amendment of 1958, clearly indicate that Congress intended to regulate substances *used* in any stage of the production of food (see generally Petition for Certiorari, pp. 13-22, 27-28), the United States would rewrite the statutory language, substantially expanding its scope, in order to encompass potential food existing in its natural state. The rationale for the Government's latitudinarian approach is contained in its novel "human act" theory. Brief in Opposition, p. 5. Thus the Government argues, in substance, that some unknown persons, for some unknown reasons, and in some unknown circumstances, intended to use DDT and dieldrin. Then, in some unknown manner, these substances found their way into Lake Michigan, and ultimately migrated to the fish in the Lake prior to the time that they were caught. From these premises, the Government leaps to the conclusion that DDT and dieldrin are "food additives" because a supposed "human act," *wholly unrelated to the production, processing, and distribution of fish,* introduced DDT

and dieldrin into the environment.* The Government reaches this conclusion notwithstanding the undisputed facts that these substances were neither used, nor intended for use, in any manner or for any purpose whatsoever in the food production and distribution process, but rather became components of fish while they existed in their natural state.

Neither the statutory language of the FDCA, nor the legislative history of the Food Additives Amendment of 1958, supports the view that a component of food, introduced in a manner entirely apart from, and unrelated to, the food production and distribution process can be considered to be a "food additive" within the meaning of the FDCA. To be sure, Congress could have written the statutory language so as to encompass any substance in a food product no matter how that substance became a component of the food. But this Congress did not do, and it is not an appropriate function of the Government, or of the Court of Appeals, to rewrite the statute in a manner so as to supply what it perceives to be Congressional omissions. *E.g.*, *Iselin* v. *United States*, 270 U.S. 245, 251 (1926); *Toilet Goods Ass'n* v. *Finch*, 419 F.2d 21, 29 (2nd Cir. 1969).

It should also be noted that the Government's "human act" theory exhibits some inconsistency, for the Government argues that "[i]t would be anomalous that a prohibi-

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* The Government distinguishes *United States* v. *1232 Cases American Brand Oysters*, 43 F. Supp. 749 (W.D. Mo. 1942), on the ground that "DDT and dieldrin do not 'inhere' in chubs in the same sense that shells inhere in oysters." Brief, p. 7. On the contrary, *American Brand*, decided adversely to the Government, is a stronger case for the Government because the shell fragments involved there resulted from the inability of the processor to remove them from the oysters during the manufacturing process. That is, the shell fragments resulted from the manufacturing process in *American Brand*. In the instant case, the presence of DDT and dieldrin in no sense resulted from the manufacturing or distribution process.

tion of the inclusion in food of an unsafe substance should turn on *which party in the food distribution chain added the substance.*" Brief, p. 6. (Emphasis added.) Such an anomaly may well exist, but it is unclear what case the Government is arguing at this point in its brief; it is certainly not this case. Not only did no one at any stage of the food production process "add" DDT and dieldrin to anything, but any "addition," even as the Government views the matter, occurred before the "food distribution chain" commenced.

3. On page 7 of its Brief in Opposition, the Government attacks Vita's contention that the terms "pesticide chemicals" and "food additives" are mutually exclusive, argues that a "pesticide chemical" in processed fish is a "food additive," and concludes that the proviso to Section 402(a)(2) of the FDCA "would be superfluous if Congress intended that substances once pesticide residues could never become food additives in processed food." Brief, p. 7 & n.8.*

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* The proviso to which the Government refers, and upon which the Court of Appeals placed considerable reliance, is contained in Section 402(a)(2)(C) of the FDCA, 21 U.S.C. § 342(a)(2)(C), and reads as follows:

"[W]here a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity...."

Wholly apart from the question of whether the concepts of "pesticide chemicals" and "food additives" are, in all circumstances, mutually exclusive, the Government's argument completely ignores Vita's contention that the DDT and dieldrin that migrated to fish in Lake Michigan are not, in the first instance, "pesticide chemicals" within the meaning of the FDCA. Petition for Certiorari, pp. 30-32. Since a "pesticide chemical" is defined as "any substance which . . . is used in the production, storage, or transportation of raw agricultural commodities," 21 U.S.C. § 321(q), and because it is undisputed that the DDT and dieldrin in question here are components of fish as they exist in their natural state before they are caught, and thus these substances are *not* "used in the production, storage, or transportation" of the fish, the DDT and dieldrin at issue here are not "pesticide chemicals" within the meaning of the FDCA, much less are they "food additives."

Moreover, Vita's analysis of the statutory scheme—which would exclude from the definitions of "food additive" and "pesticide chemical" DDT and dieldrin in the circumstances of this case—would not, as the Government contends, render the pesticide residue proviso of Section 402(a)(2)(C) superfluous. If, for example, a pesticide chemical were in fact *used* in or on a raw agricultural commodity in accordance with an exemption or tolerance level established pursuant 21 U.S.C. § 346a, and a residue of that chemical were to remain in the ultimate processed food, then the proviso would apply.* The reason that the proviso is inapplicable

* This is the situation to which Dr. Robert Smith was referring in the portion of his testimony before a Congressional subcommittee studying the food additives problem which is quoted in the footnote on page 8 of the Government's Brief. Dr. Smith stated that an "incidental food additive" would be a substance in a final product received by a consumer which was used in the food production process "such as a pesticide which is necessary in order to produce a food crop." Thus, for example, if a pesticide were

in the context of the instant case is, quite simply, that there is no sense in which it can be said that DDT and dieldrin in the present situation are *used* in or on a raw agricultural commodity, namely, fish existing in their natural state in Lake Michigan. Moreover, no exemption or tolerance level has been established for DDT or dieldrin in fish in their natural state because these substances are in no sense used on such fish.

4. The Government also contends that, in the circumstances of this case, DDT and dieldrin cannot be considered to be "accidental additives" (which concededly are not within the scope of the 1958 Food Additives Amendment) because the "presence of DDT and dieldrin in petitioner's chubs is not accidental. It is instead an inevitable consequence of a desired and intended use as pesticides." Brief, p. 8.

The Government's position that the DDT and dieldrin at issue are not "accidental additives" does not advance its argument. As noted in the Petition (p. 22), if the DDT and dieldrin may be considered "additives" *in any sense,* they are "accidental additives" because they were not used for any purpose by anyone during any stage of the manufacturing or distribution process. Vita also contended, however, that even the use of the term "accidental additive" in the present context does violence to the Congressional understanding of the additive concept, for there is no indication whatever that Congress intended the term "food

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used in the growing of apples in accordance with an exemption or tolerance level, and subsequently a residue of the pesticide remained in applesauce manufactured from the apples, then the proviso would apply. See *United States* v. *Bodine Produce Co.,* 206 F. Supp. 201, 210 (D. Ariz. 1962). See generally Petition for Certiorari, pp. 30-32.

additive" to apply to components of potential food—in this instance, fish—existing in its natural state prior to the commencement of the growing or manufacturing process.*

Moreover, the Government totally fails to explain how its interpretation of the term "food additive" is consistent with the purpose of the Food Additives Amendment of 1958, namely, to establish a pre-testing clearance program before chemical substances were used on, or in connection with, the production and distribution of food. See generally Petition for Certiorari, pp. 13-22. The elaborate procedures for obtaining prior governmental clearance for the use of "food additives" (21 U.S.C. § 348) obviously makes no sense in the context of substances that are in no manner used in connection with the production or distribution of food products, but rather unintentionally become incorporated into a potential food product existing in its natural state.

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* The very quotation from the testimony of Dr. Robert Smith (Government's Brief, p. 8) indicates that, whether or not the substances involved in the instant case can be considered to be "accidental additives," they clearly can *not* be properly termed "intentional" or "incidental" additives. Dr. Smith made clear his understanding that an "intentional additive" is a substance "added directly with knowledge that it will be in the final product, with the idea that it will impart some desirable or useful quality to the food product" and that an "incidental additive" is a substance appearing in a food product "incidental to its use somewhere back along the line of food production" or "used . . . for some purpose thought valuable in packaging . . . ." *Hearings before the Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce of the House of Representatives on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food*, 85th Cong., 2d Sess. 89-90 (1958). It is quite evident that the substances involved in the present case fall into none of these categories.

The Government's assertion that the presence of DDT and dieldrin is "an inevitable consequence of a desired and intended use as pesticides" is merely a throwback to the Government's "human act" theory, discussed at pages 3-5, *supra*. We simply emphasize (1) that Vita did not "desire" or "intend" that DDT or dieldrin be used for any purpose; (2) that Vita concededly did not "use" or "intend to use" DDT or dieldrin for any purpose; (3) that no person or persons, from the fishermen who caught the fish through the entire manufacturing and distribution process, used, desired to use, intended to use, or even inadvertently used, DDT or dieldrin in any manner or for any purpose whatsoever. In these circumstances, the substances in question here are not "food additives" within the meaning of the FDCA as illuminated and explicated by the Congressional history of the Food Additives Amendment of 1958.

## Conclusion

The Government, through its "human act" theory, seeks "not a construction of the statute, but, in effect, an enlargement of it by the court, so that what was omitted . . . may be included within its scope." *Iselin* v. *United States*, 270 U.S. 245, 251 (1926). However, even if there should exist a deficiency in the statutory scheme, "the cure must come from Congress, not by judicial enlargement of the statute." *Heater* v. *Federal Trade Commission*, 503 F.2d 321, 327 (9th Cir. 1974); *Iselin* v. *United States*, *supra*.

Because of the Government's and the Court of Appeals' effort to rewrite the statute, and the potential impact of this action upon the food industry as a whole, this case presents important questions in the administration of the Federal Food, Drug and Cosmetic Act, *62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951), which should be considered by this Court.

For all of the reasons stated herein, for the reasons stated in the Petition for Certiorari, and for the reasons stated in the Amicus Curiae Brief in Support of the Petition, Petitioner respectfully requests that a Writ of Certiorari issue to review the judgment and decision of the Court of Appeals for the Seventh Circuit.

Respectfully submitted,

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